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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,836	WERNER ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,11-28,43-49 and 70-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,11-28,43-49 and 70-82* is/are rejected.

7)☒ Claim(s) *82* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 22 March 2004 in which Figure 23 was corrected, claims 1-5, 11-28 and 43-49 were amended, claims 6-10, 29-42 and 50-69 were canceled and claims 70-82 were added. All of the amendments have been thoroughly reviewed and entered.

The previous objections and rejections in the Office Action dated 22 September, not reiterated below, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection, necessitated by amendment, are discussed.

Claims 1-5, 11-28, 43-49 and 70-82 are under prosecution.

Comments

2. The claims have been amended to define the bio-disc as having a "membrane associated with". In various embodiment, the membrane is "associated with" the active layer and/or the reflective layer. Neither the claims nor specification define the meets and bound of a membrane or the term "associated". As such, the claims are given their broadest reasonable interpretation as detailed below.

The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Smethers et al (U.S. Patent No. 5,310,523, issued 10 May 1994).

Regarding Claim 1, Smethers et al disclose a bio-disc (Fig. 2) comprising a circular substrate having a center and outer edge (reaction plate #24) an active layer associated with the substrate (solid phase #130, Fig. 14), a membrane associated with the active layer and comprising a fluidic circuit (transfer plate #28) and capture DNA immobilized on the active surface and in fluid communication with the fluidic circuit (Fig. 14 and Column 2, lines 37-67).

Regarding Claim 2, Smethers et al disclose the bio-disc wherein the capture DNA is single stranded (#132, Fig. 14A and Column 12, lines 28-44).

Regarding Claim 3, Smethers et al disclose the bio-disc wherein the capture DNA includes a double-stranded DNA i.e. captured fragment, #160 hybridized to capture probe #140 (Fig. 14B).

5. Claims 1-4, 21-24, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Besemer et al (U.S. Patent No. 5,945,334, issued 31 August 1999).

Regarding Claim 1, Besemer et al disclose a bio-disc comprising a circular substrate having a center and outer edge (i.e. round wafer, Column 4, lines 45-52) an active layer associated with the substrate (surface on which probes are attached, Column 5, lines 19-36), a membrane associated with the active layer (Column 5, lines 3-7) and comprising a fluidic circuit (channels #3411 & 3413 providing flow over chip # 3405, Column 10, lines 13-39 and Fig. 31) and capture DNA immobilized on the active surface and in fluid communication with the fluidic circuit (Column 5, lines 25-36).

Regarding Claim 2, Besemer et al disclose the bio-disc wherein the capture DNA is single stranded (Column 5, lines 25-36).

Regarding Claim 3, Besemer et al disclose the bio-disc wherein the capture DNA includes a double-stranded DNA (via hybridization, Column 18, lines 18-28).

Regarding Claim 4, Besemer et al disclose the bio-disc wherein the active layer is formed from polystyrene (Column 4, line 63).

Regarding Claim 21, Besemer et al disclose a bio-disc comprising a substrate having encoded information associated therewith (e.g. barcode, Column 6, lines 60-65) a target zone disposed at a predetermined position (e.g. alignment marks and/or arrayed probes within chamber, Column 5, lines 19-34 and Fig. 31, #3405) an active layer associated with the substrate (surface on which probes are attached, Column 5, lines 19-36), a membrane associated with the active layer (Column 5, lines 3-7) and comprising a fluidic circuit (channels #3411 & 3413 providing flow over chip # 3405, Column 10, lines 13-39 and Fig. 31) and capture DNA immobilized on the active surface and in fluid communication with the fluidic circuit (Column 5, lines 25-36). The functional language "being readable by a disc drive assembly to control rotation of the disc" is deemed an intended use for the encoded information.

The courts have stated that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed

apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Because Besemer teaches the structural limitations of the claim, they teach the device as claimed.

Regarding Claim 22, Besemer et al disclose the bio-disc wherein the capture DNA is single stranded (Column 5, lines 25-36).

Regarding Claim 23, Besemer et al disclose the bio-disc wherein the capture DNA includes a double-stranded DNA (via hybridization, Column 18, lines 18-28).

Regarding Claim 24, Besemer et al disclose the bio-disc wherein the active layer is formed from polystyrene (Column 4, line 63).

Regarding Claim 26, Besemer et al disclose a bio-disc comprising a circular substrate having a center and outer edge (i.e. round wafer, Column 4, lines 45-52) having encoded information associated therewith (e.g. barcode, Column 6, lines 60-65) a target zone disposed at a predetermined position (e.g. alignment marks and/or arrayed probes within chamber, Column 5, lines 19-34 and Fig. 31, #3405) an active layer associated with the substrate (surface on which probes are attached, Column 5, lines 19-36), a membrane associated with the active layer (Column 5, lines 3-7) and comprising a fluidic circuit (channels #3411 & 3413 providing flow over chip # 3405, Column 10, lines 13-39 and Fig. 31) and capture DNA immobilized on the active surface and in fluid communication with the fluidic circuit (Column 5, lines 25-36).

Regarding Claim 27, Besemer et al disclose a bio-disc comprising a circular substrate having a center (i.e. round wafer, Column 4, lines 45-52) having encoded information associated therewith (e.g. barcode, Column 6, lines 60-65) a target zone disposed at a predetermined position (e.g. alignment marks and/or arrayed probes within chamber, Column 5, lines 19-34 and Fig. 31, #3405) an active layer associated with the target zone (surface on which probes are attached, Column 5, lines 19-36), a capture DNA immobilized on the active

layer and viewable through the target zone (opening #3317, Fig. 31)a flow channel formed from a membrane in fluid communication with the active layer (Column 5, lines 3-7) and an input site in fluid communication with the flow channel (#3207, Fig. 31 and Column 10, lines 13-39 and Fig. 31).

6. Claims 78-81 rejected under 35 U.S.C. 102(e) as being anticipated by Curtis et al (U.S. Patent No. 4,390,499, issued 28 June 1983).

Regarding Claim 78, Curtis discloses a device comprising a circular substrate (shaft #21) and a plurality of flow channels associated with the substrate, the channels divided by a break-away wall configured to break when the disc rotates at a predetermined speed (Column 5, lines 17-67).

Regarding Claim 79, Curtis discloses the device comprising DNA immobilized on the active layer (blood serum components, Column 4, lines 48-52).

Regarding Claim 80, Curtis discloses the channels are formed of a membrane (#17 and Column 5, lines 46-49).

Regarding Claim 81, Curtis discloses the device further comprising a cap #16 associated with an inlet port #15 (Fig. 2).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-4, 11-14, 16-19, 21-24, 43-46, 70-73 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (U.S. Patent No. 5,922,617, issued 13 July 1999) in view of Smethers et al (U.S. Patent No. 5,310,523, issued 10 May 1994).

Regarding Claim 1, Wang et al disclose an optical bio-disc comprising a substantially circular substrate having a center and an outer edge, an active layer associated with the substrate and a strand of DNA including a reactive group which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 3, line 55-Column 4, line 27 and Column 8, lines 10-44). Wang et al do not teach a membrane comprising a fluidic circuit associated with active layer and immobilized DNA. However, Smethers et al disclose a similar device (Fig. 2) comprising a circular substrate having a center and outer edge (reaction plate #24) an active layer associated with the substrate (solid phase #130, Fig. 14), a membrane associated with the active layer and comprising a fluidic circuit (transfer plate #28) and capture DNA immobilized on the active surface and in fluid communication with the fluidic circuit (Fig. 14 and Column 2, lines 37-67) wherein the membrane and fluidic circuit wherein their device provides a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Wang et al with the channeled membrane of Smethers et al for the benefit of providing a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay as taught by Smethers et al (Abstract).

Regarding Claim 2, Wang et al disclose the disc wherein the DNA is a single strand (Column 4, lines 10-27).

Regarding Claim 3, Wang et al disclose the disc wherein the DNA includes a double strand i.e. after hybridization (Column 9, lines 42-48).

Regarding Claim 4, Wang et al disclose the disc wherein the active layer is formed from a modified polystyrene (Column 3, lines 65-67).

Regarding Claim 11, Wang et al disclose a bio-disc comprising substrate having a tracking groove formed therein (Column 11, lines 46-50) a reflective layer formed at least a portion of the substrate so that incident beam of electromagnetic energy may track along the groove (Column 11, lines 46-63) an active layer associated with the substrate and a strand of DNA including a reactive groups having affinity for the active layer (Column 3, line 38-Column 4, line 9). Wang et al do not teach a membrane comprising a fluidic circuit associated with active layer and immobilized DNA. However, Smethers et al disclose a similar device (Fig. 2) comprising a circular substrate having a center and outer edge (reaction plate #24) an active layer associated with the substrate (solid phase #130, Fig. 14), a membrane associated with the active layer and comprising a fluidic circuit (transfer plate #28) and capture DNA immobilized on the active surface and in fluid communication with the fluidic circuit (Fig. 14 and Column 2, lines 37-67) wherein the membrane and fluidic circuit wherein their device provides a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Wang et al with the channeled membrane of Smethers et al for the benefit of providing a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay as taught by Smethers et al (Abstract).

Regarding Claim 12, Wang et al disclose the bio-disc wherein the strand of DNA is a single strand (Column 4, lines 10-27).

Regarding Claim 13, Wang et al disclose the bio-disc wherein the DNA includes a double strand i.e. after hybridization (Column 9, lines 42-48).

Regarding Claim 14, Wang et al disclose the bio-disc wherein the active layer is formed from a modified polystyrene (Column 3, lines 65-67).

Regarding Claim 16, Wang et al disclose an optical bio-disc comprising a substantially circular substrate having a center and an outer edge, an active layer associated with the substrate and a strand of DNA including a reactive group which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 3, line 38-Column 4, line 9) wherein the reactive groups is an amino reactive group (Column 4, lines 2-5) and a reflective layer (Column 11, lines 46-50). Wang et al do not teach a membrane comprising a fluidic circuit associated with active layer and immobilized DNA. However, Smethers et al disclose a similar device (Fig. 2) comprising a circular substrate having a center and outer edge (reaction plate #24) an active layer associated with the substrate (solid phase #130, Fig. 14), a membrane associated with the active layer and comprising a fluidic circuit (transfer plate #28) and capture DNA immobilized on the active surface and in fluid communication with the fluidic circuit (Fig. 14 and Column 2, lines 37-67) wherein the membrane and fluidic circuit wherein their device provides a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Wang et al with the channeled membrane of Smethers et al for the benefit of providing a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay as taught by Smethers et al (Abstract).

Regarding Claim 17, Wang et al disclose the bio-disc wherein the strand of DNA is a single strand (Column 4, lines 10-27).

Regarding Claim 18, Wang et al disclose the bio-disc wherein the DNA includes a double strand i.e. after hybridization (Column 9, lines 42-48).

Regarding Claim 19, Wang et al disclose the bio-disc wherein the active layer is formed from a modified polystyrene (Column 3, lines 65-67).

Regarding Claim 21, Wang et al disclose an optical bio-disc comprising a substrate having encoded information associated therewith, said information being readable by a disc

drive assembly to control rotation (Column 10, line 20-Column 11, line 9); a target zone associated with the substrate and disposed at a predetermined location; an active layer associated with the target zone and a strand of DNA including a reactive group which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 3, line 38-Column 4, line 9). Wang et al do not teach a membrane comprising a fluidic circuit associated with active layer and immobilized DNA. However, Smethers et al disclose a similar device (Fig. 2) comprising a circular substrate having a center and outer edge (reaction plate #24) an active layer associated with the substrate (solid phase #130, Fig. 14), a membrane associated with the active layer and comprising a fluidic circuit (transfer plate #28) and capture DNA immobilized on the active surface and in fluid communication with the fluidic circuit (Fig. 14 and Column 2, lines 37-67) wherein the membrane and fluidic circuit wherein their device provides a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Wang et al with the channeled membrane of Smethers et al for the benefit of providing a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay as taught by Smethers et al (Abstract).

Regarding Claim 22, Wang et al disclose the bio-disc wherein the strand of DNA is a single strand (Column 4, lines 10-27).

Regarding Claim 23, Wang et al disclose the bio-disc wherein the DNA includes a double strand i.e. after hybridization (Column 9, lines 42-48).

Regarding Claim 24, Wang et al disclose the bio-disc wherein the active layer is formed from a modified polystyrene (Column 3, lines 65-67).

Regarding Claim 43, Wang et al disclose an optical bio-disc comprising a substrate having a center and an outer edge, said substrate having a top and a bottom surface, a reflective layer formed on the bottom surface, an active layer associated with the substrate and

reflective layer (Column 10, lines 37-40) and a strand of DNA including a reactive group (e.g. avidin) which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 3, line 38-Column 4, line 9). Wang et al further teach the reflective layer (header) defines target zones (Column 10, lines 20-42, especially lines 37-42).

Regarding Claim 44, Wang et al disclose the bio-disc wherein the strand of DNA is a single strand (Column 4, lines 10-27). The recitation "which includes a reporter that is detectable by said interrogation beam" describes characteristics of a target strand but does not describe structural components of the bio-disc. As such, the recitation does not further limit the claim.

Regarding Claim 45, Wang et al disclose the bio-disc wherein the DNA includes a double strand i.e. after hybridization (Column 9, lines 42-48).

Regarding Claim 46, Wang et al disclose the bio-disc wherein the active layer is formed from a modified polystyrene (Column 3, lines 65-67).

Regarding Claim 47, Wang et al disclose the bio-disc wherein the substrate is modified polystyrene (Column 3, line 65-Column 4, line 9).

Regarding Claim 49, Wang et al disclose the bio-disc wherein the reflective layer is interposed between the substrate and active layer e.g. in grooves or pits (Column 10, lines 40-42).

Regarding Claim 70, Wang et al disclose a bio-disc comprising a circular substrate a reflective layer associated with the substrate, a plurality of target zones disposed in the reflective layer wherein the reflective layer is in recessed portions of the substrate e.g. pits or groves and an active layer associated with the reflective layer (Column 10, line 20-Column 11, line 9 and Fig. 5-7). The claims are broadly drawn to a device defined by its functionality and associations e.g. to transmit interrogation beam, to reflect interrogation beam, permits interrogation and etc. While Wang does not teach the claimed functionality the illumination

illustrated in Fig. 7 clearly suggests interrogation beams as claimed. The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114).

Regarding Claim 71-12, Wang et al do not teach a membrane comprising a fluidic circuit associated with active layer and immobilized DNA. However, Smethers et al disclose a similar device (Fig. 2) comprising a circular substrate having a center and outer edge (reaction plate #24) an active layer associated with the substrate (solid phase #130, Fig. 14), a membrane associated with the active layer and comprising a fluidic circuit (transfer plate #28) and capture DNA immobilized on the active surface and in fluid communication with the fluidic circuit (Fig. 14 and Column 2, lines 37-67) wherein the membrane and fluidic circuit wherein their device provides a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Wang et al with the channeled membrane of Smethers et al for the benefit of providing a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay as taught by Smethers et al (Abstract).

Regarding Claim 73, Smethers et al teach the membrane is adhesive i.e. elastomeric seals (Column 8, lines 16-31).

Regarding Claim 76, Smethers et al teach the device further comprising a cap providing an inlet port (#52 a-c, Fig 3).

9. Wang et al (U.S. Patent No. 5,922,617, issued 13 July 1999) in view of Smethers et al (U.S. Patent No. 5,310,523, issued 10 May 1994) as applied to Claim 70 above and further in view of Besemer et al (U.S. Patent No. 5,945,334, issued 31 August 1999).

Regarding Claims 74-75, Wang et al disclose a bio-disc comprising a circular substrate a reflective layer associated with the substrate, a plurality of target zones disposed in the reflective layer wherein the reflective layer is in recessed portions of the substrate e.g. pits or groves and an active layer associated with the reflective layer (Column 10, line 20-Column 11, line 9 and Fig. 5-7) and Smethers et al teach membranes having fluidic circuits but do not teach flow channel and return channel having "U" shape. However, these fluidic channels were well known in the art at the time the claimed invention was made as taught by Besemer et al who teach their channels provide for even distribution of reagents over the analyte surface (Column 10, lines 25-39 and Fig. 31). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the channels of Besemer to the device of Wang and Smethers et al for the expected benefit of providing even distribution of the reagents as desired in the art (Besemer, column 10, lines 25-39).

10. Claims 5, 15, 20, 25 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (U.S. Patent No. 5,922,617, issued 13 July 1999) in view of in view of Smethers et al (U.S. Patent No. 5,310,523, issued 10 May 1994) as discussed above and further in view of Charles et al (U.S. Patent No. 5,436,972, issued 8 August 1995) and/or Jan et al (U.S. Patent No. 6,403,368, filed 25 October 2000).

Regarding Claims 5, 10, 15, 20, 25 and 48, Wang et al disclose a bio-disc comprising substrate having a tracking groove formed therein (Column 11, lines 46-50) a reflective layer formed at least a portion of the substrate so that incident beam of electromagnetic energy may

track along the groove (Column 11, lines 46-63) an active layer associated with the substrate and a strand of DNA including a reactive groups having affinity for the active layer (Column 3, line 38-Column 4, line 9) wherein the substrate is modified polystyrene having any one of a variety of functionalities (Column 3, line 65-Column 4, line 9) but they do not specifically teach polystyrene is polystyrene-co-maleic anhydride. However, substrates comprising polystyrene-co-maleic anhydride were well known in the art at the time the claimed invention was made as taught by Charles et al and Jan et al.

Charles et al teach substrates comprising polystyrene-co-maleic anhydride (Column 6, lines 1-37) and they teach their substrates provide for direct immobilization of biological molecules (e.g. DNA) and eliminate the need for activation prior to immobilization (Column 2, lines 26-31). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the polystyrene-co-maleic anhydride substrates of Charles et al to the modified polystyrene substrates of Wang et al to thereby simplify immobilization by eliminating a step of activation prior to immobilization as taught by Charles et al (Column 2, lines 26-31).

Additionally, Jan et al teach substrates comprising polystyrene-co-maleic anhydride (Column 5, lines 36-40) wherein their modified substrates provide "one-step" immobilization thereby greatly reducing the time required for immobilization (Column 6, lines 12-37). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the polystyrene-co-maleic anhydride substrates of Jan et al to the polystyrene modified substrates of Wang et al thereby providing "one-step" immobilization for the expected benefit of greatly reducing the time required for immobilization as taught by Jan et al (Column 6, lines 32-36).

11. Claims 1-3, 11-13, 16-18, 21-23, 26-28, 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen (U.S. Patent No. 6,342,349, filed 21 July 1998).

Regarding Claim 1, Virtanen discloses an optical bio-disc comprising a substantially circular substrate having a center and an outer edge, an active layer associated with the substrate and a strand of DNA including a reactive group which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 5, lines 14-42 and Column 16, lines 51-65).

Virtanen does not teach a membrane comprising a fluidic circuit associated with active layer and immobilized DNA. However, Smethers et al disclose a similar device (Fig. 2) comprising a circular substrate having a center and outer edge (reaction plate #24) an active layer associated with the substrate (solid phase #130, Fig. 14), a membrane associated with the active layer and comprising a fluidic circuit (transfer plate #28) and capture DNA immobilized on the active surface and in fluid communication with the fluidic circuit (Fig. 14 and Column 2, lines 37-67) wherein the membrane and fluidic circuit wherein their device provides a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Virtanen et al with the channeled membrane of Smethers et al for the benefit of providing a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay as taught by Smethers et al (Abstract).

Regarding Claim 2, Virtanen discloses the disc wherein the DNA is a single strand (Column 16, lines 51-65).

Regarding Claim 3, Virtanen discloses the disc wherein the DNA includes a double strand i.e. after hybridization (Column 16, lines 51-65).

Regarding Claim 6, Virtanen discloses a surface assembly comprising a substrate, an active layer associated with the substrate and a strand of DNA including a reactive group (e.g. avidin) which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 5, lines 14-42 and Column 16, lines 51-65).

Regarding Claim 7, Virtanen discloses the disc wherein the DNA is a single strand (Column 16, lines 51-65).

Regarding Claim 8, Virtanen discloses the disc wherein the DNA includes a double strand i.e. after hybridization (Column 16, lines 51-65).

Regarding Claim 11, Virtanen discloses a bio-disc comprising substrate having a tracking groove formed therein (Column 11, lines 46-50) a reflective layer formed at least a portion of the substrate so that incident beam of electromagnetic energy may track along the groove (Column 11, lines 46-63) an active layer associated with the substrate and a strand of DNA including a reactive groups having affinity for the active layer (Column 5, lines 14-42 and Column 16, lines 51-65).

Virtanen does not teach a membrane comprising a fluidic circuit associated with active layer and immobilized DNA. However, Smethers et al disclose a similar device (Fig. 2) comprising a circular substrate having a center and outer edge (reaction plate #24) an active layer associated with the substrate (solid phase #130, Fig. 14), a membrane associated with the active layer and comprising a fluidic circuit (transfer plate #28) and capture DNA immobilized on the active surface and in fluid communication with the fluidic circuit (Fig. 14 and Column 2, lines 37-67) wherein the membrane and fluidic circuit wherein their device provides a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Virtanen et al with the channeled membrane of Smethers et al for the benefit of providing a self-contained assembly for

sequential addition of multiple reagents in an analyte detection assay as taught by Smethers et al (Abstract).

Regarding Claim 12, Virtanen discloses the disc wherein the DNA is a single strand (Column 16, lines 51-65).

Regarding Claim 13, Virtanen discloses the disc wherein the DNA includes a double strand i.e. after hybridization (Column 16, lines 51-65).

Regarding Claim 16, Virtanen discloses an optical bio-disc comprising a substantially circular substrate having a center and an outer edge, an active layer associated with the substrate and a strand of DNA including a reactive group which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 5, lines 14-42 and Column 16, lines 51-65) wherein the reactive groups is an amino reactive group (Column 42, lines 16-17).

Virtanen does not teach a membrane comprising a fluidic circuit associated with active layer and immobilized DNA. However, Smethers et al disclose a similar device (Fig. 2) comprising a circular substrate having a center and outer edge (reaction plate #24) an active layer associated with the substrate (solid phase #130, Fig. 14), a membrane associated with the active layer and comprising a fluidic circuit (transfer plate #28) and capture DNA immobilized on the active surface and in fluid communication with the fluidic circuit (Fig. 14 and Column 2, lines 37-67) wherein the membrane and fluidic circuit wherein their device provides a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Virtanen et al with the channeled membrane of Smethers et al for the benefit of providing a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay as taught by Smethers et al (Abstract).

Regarding Claim 17, Virtanen discloses the disc wherein the DNA is a single strand (Column 16, lines 51-65).

Regarding Claim 18, Virtanen discloses the disc wherein the DNA includes a double strand i.e. after hybridization (Column 16, lines 51-65).

Regarding Claim 21, Virtanen discloses an optical bio-disc comprising a substrate having encoded information associated therewith, said information being readable by a disc drive assembly to control rotation (Column 10, line 20-Column 11, line 9); a target zone associated with the substrate and disposed at a predetermined location; an active layer associated with the target zone and a strand of DNA including a reactive group which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 5, lines 14-42 and Column 16, lines 51-65) wherein the reactive groups is an amino reactive group (Column 42, lines 16-17).

Virtanen does not teach a membrane comprising a fluidic circuit associated with active layer and immobilized DNA. However, Smethers et al disclose a similar device (Fig. 2) comprising a circular substrate having a center and outer edge (reaction plate #24) an active layer associated with the substrate (solid phase #130, Fig. 14), a membrane associated with the active layer and comprising a fluidic circuit (transfer plate #28) and capture DNA immobilized on the active surface and in fluid communication with the fluidic circuit (Fig. 14 and Column 2, lines 37-67) wherein the membrane and fluidic circuit wherein their device provides a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Virtanen et al with the channeled membrane of Smethers et al for the benefit of providing a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay as taught by Smethers et al (Abstract).

Regarding Claim 22, Virtanen discloses the disc wherein the DNA is a single strand (Column 16, lines 51-65).

Regarding Claim 23, Virtanen discloses the disc wherein the DNA includes a double strand i.e. after hybridization (Column 16, lines 51-65).

Regarding Claims 26-30, Virtanen discloses an optical bio-disc comprising a substrate having a center and an outer edge having encoded information associated therewith, said encoded information being readable by a disc drive assembly to control rotation of the disc, a target zone associated with the substrate said target zone disposed at a predetermined location relative to the center of the substrate, an active layer associated with the target zone, a strand of capture DNA including a reactive group for immobilization within the target zone, a flow channel in fluid communication with the target zone and a plurality of reporters deposited in the flow channel and a an input site in fluid communication with the flow channel for receiving sample DNA (Fig. 19 and 40).

Regarding Claim 43, Virtanen discloses an optical bio-disc comprising a substrate having a center and an outer edge, said substrate having a top and a bottom surface, a reflective layer formed on the bottom surface, an active layer associated with the substrate and reflective layer (Column 10, lines 37-40) and a strand of DNA including a reactive group (e.g. avidin) which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 5, lines 14-42 and Column 16, lines 51-65) wherein the reactive groups is an amino reactive group (Column 42, lines 16-17).

Virtanen does not teach a membrane comprising a fluidic circuit associated with active layer and immobilized DNA. However, Smethers et al disclose a similar device (Fig. 2) comprising a circular substrate having a center and outer edge (reaction plate #24) an active layer associated with the substrate (solid phase #130, Fig. 14), a membrane associated with the active layer and comprising a fluidic circuit (transfer plate #28) and capture DNA immobilized on the active surface and in fluid communication with the fluidic circuit (Fig. 14 and Column

2, lines 37-67) wherein the membrane and fluidic circuit wherein their device provides a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Virtanen et al with the channeled membrane of Smethers et al for the benefit of providing a self-contained assembly for sequential addition of multiple reagents in an analyte detection assay as taught by Smethers et al (Abstract).

Regarding Claim 44, Virtanen discloses the disc wherein the DNA is a single strand (Column 16, lines 51-65).

Regarding Claim 45, Virtanen discloses the disc wherein the DNA includes a double strand i.e. after hybridization (Column 16, lines 51-65).

Double Patenting

Reiterated from previous Office Action

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 11-15 and 21-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-66 of copending Application No. 10/086,941. Although the conflicting claims are not identical, they are not

patentably distinct from each other because both sets of claims are drawn to optical bio-disc comprising very similar elements and differ only in the arrangement of the limitations. For example, instant Claim 11 is drawn to bio-disc comprising a strand of DNA while Claim 29 of the '941 application is drawn to a bio-disc comprising a capture agent and dependent Claim 30 is drawn to a DNA capture agent. As such, both sets of claims are drawn to bio-disc having the same and/or very similar scope. Therefore the sets of claims are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Allowable Subject Matter

15. Claim 82 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
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